



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 16 1999

NADA 120-161

Mr. Thomas R. Schriemer, Manager
Worldwide Animal Health Regulatory Affairs
Pharmacia & Upjohn
7000 Portage Road (Unit 9691-190-43)
Kalamazoo, MI 49001-0199

Dear Mr. Schriemer:

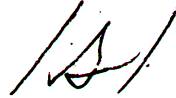
We have become aware of an advertisement which appeared in the July 1999, edition of Veterinary Economics for ANTIROBE®, NADA 120-161. The advertisement appeared twice in the journal, on page 22 and page 17 of the supplement. We have also reviewed the Why Antirobe? advertisement (declared and) submitted on FORM FDA 2301 dated May 11, 1999. We find these advertisements to be in violation of FDA advertising regulations.

The advertisements fail to present a fair balance of information relating to side effects and contraindications with a scope, depth, and detail reasonably comparable with the presentation of information relating to the effectiveness of the drug in the body of the text [21 CFR §202.1(e)(5)(ii)]. The advertisements also fail to include the established name, "Clindamycin Hydrochloride," as required [21 CFR §202.1(b)(1)]. The use of such phrases as "...periodontal disease..Antirobe® Capsules/Aquadrops® Liquid, Pharmacia & Upjohn offers everything you need..." in the Veterinary Economics journal advertisement make representation or suggestion about the use of Antirobe®. For this reason, we consider this to be a full product advertisement. Thus, the advertisement fails to present a true statement of information in brief summary relating to side effects, contraindications, and effectiveness [21 CFR §202.1(e)(1)]. It also fails to provide adequate information regarding the product's approved indication and usage. In addition, our records do not indicate that Pharmacia & Upjohn submitted the aforementioned as an advertisement on Form FDA 2301, thus violating the postmarketing reporting requirements [21 CFR 510.300(b)(3)].

We ask that the advertisements cited in this letter, and other similar ones intended for future dissemination, be immediately stopped. In addition, we request that you review your company policies to give due consideration and attention to promotional practices and ensure that your promotional materials comply with the requirements of FDA regulations.

Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6639.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'V. Vengris', written over a horizontal line.

Vitolis Vengris, D.V.M., Ph.D.
Marketed Product Scientific and
Regulatory Review, Team 1,
HFV-214
Division of Surveillance
Center for Veterinary Medicine